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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,220	06/08/2001	Karin Westlund High	265.0019 0101	8535

26813 7590 10/02/2002

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MINNEAPOLIS, MN 55458

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/877,220**

Applicant(s)  
**High et al.**

Examiner  
**Michael Brannock, Ph.D**

Art Unit  
**1646**

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 21, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-31 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-19, 25-28, drawn to methods of treating a neuropathic state in a subject, classification dependent on the chemical identity of the compound to be administered.
  - II. Claims 20, 21, 24, 29-31, drawn to methods of identifying compounds that alter the NR1 subunit distribution in a cell, classified in class 436, subclass 501.
  - III. Claim 22 and 23, drawn to methods of identifying compounds that alter the TNF $\alpha$  production of a cell, classified in class 435, subclass 7.2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-III are directed to methods that are distinct both physically and functionally, are not required one for the other, require different starting materials, and accomplish different goals. Group I requires methods of treatment of a subject, which is not required by any of the other groups. Group II requires an assay of subcellular localization of

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NR1, which is not required by any of the other groups. Group III requires a quantitative assay of extracellular TNF $\alpha$  production, which is not required by any of the other groups.

3. Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

4. Claims 1-19, 25-31 are generic to a plurality of disclosed patentably distinct species comprising methods of administering particular molecules described as tyrosine kinase inhibitors or other compounds that alter the TNF $\alpha$  production, e.g. Genistein, Lavendustin A, K252a, etc. Each method involves the use of a chemically distinct compound, the use of one not being required for the use of another. Further, although a search of any one of the species may overlap that of another, the search of one species could not be relied upon, solely, to provide art that is anticipatory or would render obvious the invention of any other species, and to search all species would be burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species consisting of the administration of a single particular molecule, even though this requirement is traversed. Applicant is also required to provide a listing of all claims readable thereon, including any claims subsequently added.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims 1-19, 25 and 26 are generic to a plurality of disclosed patentably distinct species comprising methods of treating each of a variety of disparate disease states, e.g. persistent pain, arthritis, ulcerative colitis, inflammatory bowel disease, Crohn's disease, pancreatitis, asthma, stroke, brain injury, spinal cord injury, epileptogenesis, viral invasion, etc. Each method involves distinct patient populations, the use of one not being required for the any other. Further, although a search of any one of the species may overlap that of another, the search of one species could not be relied upon, solely, to provide art that is anticipatory or would render obvious the invention of any other species, and to search all species would be burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species consisting of the treatment of a single identifiable patient population, even though this requirement is traversed. Applicant is also required to provide a listing of all claims readable thereon, including any claims subsequently added.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention that includes an election of either Group I-III, an election of a species of compound to be administered, and an election of species of disorder if Group I is elected, to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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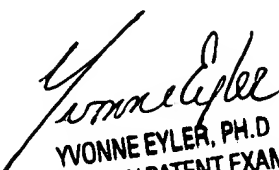
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



October 1, 2002



YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600